§ 121.6 Organ procurement.

The suitability of organs donated for transplantation shall be determined as follows:

(a) *Tests.* An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.

(b) *HIV.* Organs from individuals known to be infected with human immunodeficiency virus shall not be procured for transplantation.

(c) *Acceptance criteria.* Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.

§ 121.7 Identification of organ recipient.

(a) *List of potential transplant recipients.* (1) An OPTN member procuring an organ shall operate the OPTN computer match program within such time as the OPTN may prescribe to identify and rank potential recipients for each cadaveric organ procured.

(2) The rank order of potential recipients shall be determined for each cadaveric organ using the organ specific allocation criteria established in accordance with § 121.8.

(3) When a donor or donor organ does not meet a transplant program's donor acceptance criteria, as established under § 121.6(c), transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.

(b) *Offer of organ for potential recipients.* (1) Organs shall be offered for potential recipients in accordance with policies developed under § 121.8 and implemented under § 121.4.

(2) Organs may be offered only to potential recipients listed with transplant programs having designated transplant programs of the same type as the organ procured.

(3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.

(4) A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant program shall document and provide to the OPO and to the OPTN the reasons for refusal and shall maintain this document for one year.

(c) *Transportation of organ to potential recipient*—(1) *Transportation.* The OPTN member that procures a donated organ shall arrange for transportation of the organ to the transplant hospital.

(2) *Documentation.* The OPTN member that is transporting an organ shall assure that it is accompanied by written documentation of activities conducted to determine the suitability of the organ donor and shall maintain this document for one year.

(3) *Packaging.* The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) *Receipt of an organ.* Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in accordance with paragraph (b) of this section.

(e) *Wastage.* Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe.

§ 121.8 Allocation of organs.

(a) *Policy development.* The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process under § 121.4, organ-specific policies (including combinations of organs, such as for heart-

lung transplants) for the equitable allocation of cadaveric organs among potential recipients. Such policies shall meet the requirements in paragraphs (a)(1), (2), (3), (4) and (5) of this section. Such policies shall be reviewed periodically and revised as appropriate.

(1) Minimum listing criteria for including transplant candidates on the national list shall be standardized and, to the extent possible, shall contain explicit thresholds for listing a patient and be expressed through objective and measurable medical criteria.

(2) Transplant candidates shall be grouped by status categories ordered from most to least medically urgent, with a sufficient number of categories to avoid grouping together persons with substantially different medical urgency. Criteria for status designations shall contain explicit thresholds for differentiating among patients and shall be expressed, to the extent possible, through objective and measurable medical criteria.

(3) Organ allocation policies and procedures shall be in accordance with sound medical judgment and shall be designed and implemented:

(i) To allocate organs among transplant candidates in order of decreasing medical urgency status, with waiting time in status used to break ties within status groups. Neither place of residence nor place of listing shall be a major determinant of access to a transplant. For each status category, inter-transplant program variance in the performance indicator ''waiting time in status'' shall be as small as can reasonably be achieved, consistent with paragraph (a)(3)(ii) of this section. Priority shall be given to reducing the waiting time variance in the most medically urgent status categories before reducing the waiting time variance in less urgent status categories, if equivalent reductions cannot be achieved in all status categories; and

(ii) To avoid futile transplantation, to avoid wasting organs, and to promote efficient management of organ placement.

(4) The OPTN shall:

(i) Develop mechanisms to promote and review compliance with each of these goals;

(ii) Develop performance indicators to facilitate assessment of how well current and proposed policies will accomplish these goals;

(iii) Use performance indicators, including indicators described in paragraph (a)(4)(iv) of this section, to establish baseline data on how closely the results of current policies approach these goals and to establish the projected amount of improvement to result from proposed policies; and

(iv) Timely report data to the Secretary on performance by organ and status category, including program-specific data, OPO specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include inter-transplant program variation in waiting time in status, total life years pre- and post-transplant, patient and graft survival rates following transplantation, patients mis-classified by status, and number of patients who die waiting for a transplant. Such data shall cover such intervals of time, and be presented using confidence intervals or other measures of variance, as appropriate to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(5) *Transition*—(i) *General.* When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the national list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(ii) *Special rule for initial revision of liver allocation policies.* When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (c)(2) of this section, it shall include transition procedures that, to the extent feasible, treat each individual on the national list and awaiting transplantation on April 2, 1998 no less favorably than he or she would have been treated had the

revised liver allocation policies not become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after accommodating a substantial preponderance of those disadvantaged by the change in the policies.

(b) *Secretarial review of policies and performance Indicators.* The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraph (a) of this section.

(c) *Deadlines for initial reviews.* (1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (c)(2) of this section, no later than October 1, 1999 transmit initial revised policies to meet the requirements of §121.8 (a), together with supporting documentation to the Secretary for review in accordance with §121.4.

(2) No later than November 30, 1998 the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements of §121.8 (a) to the Secretary for review in accordance with §121.4. The OPTN may transmit these materials without seeking further public comment under §121.4(b) or (c).

(d) *Variances.* The OPTN may develop experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of §121.4.

(e) *Directed donation.* Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.

[63 FR 16332, Apr. 2, 1998, as amended at 63 FR 35847, July 1, 1998]

§121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare and Medicaid; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4;

(iv) Has available operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel;

(v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;

(vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and

(vii) Makes available psychiatric and social support services for transplant candidates, transplant recipients and their families; or

(3) Be a transplant program in a Department of Veterans Affairs hospital which is a Dean's Committee hospital which shares a common university-based transplant team of a transplant